I

118TH CONGRESS
1ST SESSION

H. R. 1418

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

IN THE HOUSE OF REPRESENTATIVES

MARCH 7, 2023

Mr. PENCE (for himself and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug User Fee Amendments of 2023''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is the following:

TITLE I—FEES RELATING TO ANIMAL DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Animal Drug User Fee Amendments of 2023''.

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 739(8)(I) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11(8)(I)) is amended to read as follows:

''(I) The activities necessary for implementation of the United States and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the United States and United Kingdom Recognition Agreement Sectoral Annex for Pharmaceutical Good Manufacturing Practices, and future mutual recognition agreements, with respect to animal drug products subject to review, including implementation activities prior to and following product approval.''.

SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Section 740(a)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(a)(1)(A)(ii)) is amended—

(1) in subclause (I), by striking ''and'' at the end;

(2) in subclause (II), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

"(III) an application for conditional approval under section 571 of a new animal drug for which an animal drug application submitted under section 512(b)(1) has been previously approved under section 512(d)(1) for another intended use.".

(b) FEE REVENUE AMOUNTS.—Section 740(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(b)(1)) is amended to read as follows:

"(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g), for each of fiscal years 2024 through 2028, the fees required under subsection (a) shall be established to generate a total revenue amount of $33,500,000.".

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) ANNUAL FEE SETTING.—Section 740(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(c)(1)) is amended to read as follows:

"(1) ANNUAL FEE SETTING.—Not later than 60 days before the start of each fiscal year beginning after September 30, 2023, the Secretary shall—

"(A) establish for that fiscal year animal drug application fees, supplemental animal drug

application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

''(B) publish such fee revenue amounts and fees in the Federal Register.''.

(2) INFLATION ADJUSTMENT.—Section 740(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(c)(2)) is amended—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''2020'' and inserting ''2025''; and

(ii) in clause (iii), by striking ''Baltimore'' and inserting ''Arlington-Alexandria''; and

(B) in subparagraph (B), by striking ''2020'' and inserting ''2025''.

(3) WORKLOAD ADJUSTMENTS.—Paragraph (3) of section 740(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(c)) is amended—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i)—

(I) by striking ''2020'' and inserting ''2025''; and

(II) by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraph (B)'';

(ii) in clause (i) by striking ''and'' at the end; and

(iii) by striking clause (ii) and inserting the following:

''(ii) such adjustment shall be made for each fiscal year that the adjustment determined by the Secretary is greater than 3 percent, except for the first fiscal year that the adjustment is greater than 3 percent; and

''(iii) the Secretary shall publish in the Federal Register notice under paragraph (1) the amount of such adjustment and the supporting methodologies.'';

(B) by striking subparagraph (B); and

(C) by redesignating subparagraph (C) as subparagraph (B).

(4) FINAL YEAR ADJUSTMENT.—Section 740(c)(4) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 379j–12(c)(4)) is amended to read as follows:

''(4) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2025 and each subsequent fiscal year, after the fee revenue amount established under subsection (b) is adjusted in accordance with paragraphs (2) and (3), the Secretary shall—

''(i) increase the fee revenue amount for such fiscal year, if necessary to provide an operating reserve of not less than 12 weeks; or

''(ii) if the Secretary has an operating reserve in excess of the number of weeks specified in subparagraph (C) for that fiscal year, the Secretary shall decrease the fee revenue amount to provide not more than the number of weeks specified in subparagraph (C) for that fiscal year.

''(B) CARRYOVER USER FEES.—For purposes of this paragraph, the operating reserve of carryover user fees for the process for the review of animal drug applications does not include carryover user fees that have not been appropriated.

"(C) NUMBER OF WEEKS OF OPERATING RESERVES.—The number of weeks of operating reserves specified in this subparagraph is—

"(i) 22 weeks for fiscal year 2025;

"(ii) 20 weeks for fiscal year 2026;

"(iii) 18 weeks for fiscal year 2027; and

"(iv) 16 weeks for fiscal year 2028.

"(D) PUBLICATION.—If an adjustment to the operating reserve is made under this paragraph, the Secretary shall publish in the Federal Register notice under paragraph (1) the rationale for the amount of the adjustment and the supporting methodologies.".

(d) EXEMPTION FROM FEES.—Section 740(d)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(d)(4)) is amended to read as follows:

"(4) EXEMPTION FROM FEES FOR CERTAIN ANIMAL DRUG APPLICATIONS.—Fees under paragraphs (2), (3), and (4) of subsection (a) shall not apply with respect to any person who is the named applicant or sponsor of an animal drug application, supplemental animal drug application, or investigational animal drug submission if such application or submission involves the intentional genomic alter-

ation of an animal that is intended to produce a drug, device, or biological product subject to fees under section 736, 738, 744B, or 744H.''.

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 740(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(g)(3)) is amended by striking ''2019 through 2023'' and inserting ''2024 through 2028''.

(2) COLLECTION SHORTFALLS.—Section 740(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(g)) is amended—

(A) in paragraph (3), by striking ''and paragraph (5)''; and

(B) by striking paragraph (5).

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) is amended—

(1) in subsection (a), by striking ''2018'' and inserting ''2023'';

(2) by striking ''2019'' each place it appears in subsections (a) and (b) and inserting ''2024''; and

(3) in subsection (d)—

(A) in paragraph (1), by striking ''2023'' and inserting ''2028''; and

(B) in paragraph (5), by striking ''2023'' and inserting ''2028''.

SEC. 105. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on the day before the date of enactment of this title, shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after October 1, 2018, but before October 1, 2023, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2024.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2023, or the date of the enactment of this Act, whichever is later, except that fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this title, shall be assessed for animal drug applications and supplemental animal drug applications received on or after October 1, 2023, regardless of the date of the enactment of this Act.

SEC. 107. SUNSET DATES.

(a) AUTHORIZATION.—Sections 739 and 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall cease to be effective October 1, 2028.

(b) REPORTING REQUIREMENTS.—Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) shall cease to be effective January 31, 2029.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2023, subsections (a) and (b) of section 107 of the Animal Drug User Fee Amendments of 2018 (Public Law 115–234) are repealed.

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

SEC. 201. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Animal Generic Drug User Fee Amendments of 2023''.

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified for purposes of part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of

Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor and Pensions of the Senate as set forth in the Congressional Record.

SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Section 741(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(a)) is amended by adding at the end the following:

''(4) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE FEE.—

''(A) IN GENERAL.—

''(i) ASSESSMENT OF FEE.—Each person that submits a request to establish a generic investigational new animal drug file on or after October 1, 2023, shall be assessed a fee as established under subsection (c).

''(ii) EXISTING FILES.—In the case of a generic investigational new animal drug file established prior to October 1, 2023, each person that makes a submission to such a file on or after October 1, 2023, shall be assessed a fee for the first submis-

sion on or after October 1, 2023, as established under subsection (c).

''(B) PAYMENT.—The fee required by subparagraph (A)(i) shall be due upon submission of the request to establish the generic investigational new animal drug file. The fee required by subparagraph (A)(ii) shall be due upon the first submission to the generic investigational new animal drug file.

''(C) EXCEPTIONS.—

''(i) TERMINATION.—If a person makes a submission to the generic investigational new animal drug file to terminate that file, the person shall not be subject to a fee under subparagraph (A)(ii) for that submission.

''(ii) TRANSFERS.—If a person makes a submission to the generic investigational new animal drug file to transfer that file to a different generic new animal drug sponsor, the person shall not be subject to a fee under subparagraph (A)(ii) for that submission.''.

(b) FEE REVENUE AMOUNTS.—Section 741(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(b)) is amended—

(1) in paragraph (1)—

(A) by striking ''2019 through 2023'' and inserting ''2024 through 2028''; and

(B) by striking ''$18,336,340'' and inserting ''$25,000,000''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) by striking ''25 percent'' and inserting ''20 percent''; and

(ii) by inserting before the semicolon at the end the following: ''and subsection (a)(4) (relating to generic investigational new animal drug files)'';

(B) in subparagraph (B), by striking ''37.5 percent'' and inserting ''40 percent''; and

(C) in subparagraph (C), by striking ''37.5 percent'' and inserting ''40 percent''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) ANNUAL FEE SETTING.— Section 741(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(c)(1)) is amended to read as follows:

''(1) ANNUAL FEE SETTING.—The Secretary shall establish, not later than 60 days before the start of each fiscal year beginning after September 30, 2023, for that fiscal year—

''(A) abbreviated application fees that are based on the revenue amounts established under subsection (b), the adjustments provided under this subsection, and the amount of fees anticipated to be collected under subsection (a)(4) during that fiscal year;

''(B) generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

''(C) a generic investigation new animal drug file fee of $50,000 for each request or submission covered by subsection (a)(4)(A).''.

(2) INFLATION ADJUSTMENT.—Section 741(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(c)(2)) is amended—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''2020'' and inserting ''2025''; and

(ii) in clause (iii), by striking ''Baltimore'' and inserting ''Arlington-Alexandria''; and

(B) in subparagraph (B), by striking ''2020'' and inserting ''2025''.

(3) WORKLOAD ADJUSTMENT.—Section 741(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(c)(3)) is amended—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''2020'' and inserting ''2025'';

(ii) in clause (i)—

(I) by striking ''and investigational generic new animal drug protocol submissions'' and inserting ''investigational generic new animal drug protocol submissions, requests to establish a generic investigational new animal drug file, and generic investigational new animal drug meeting requests''; and

(II) by striking ''; and'' and inserting a semicolon;

(iii) by redesignating clause (ii) as clause (iii); and

(iv) by inserting after clause (i) the following:

''(ii) if the workload adjustment calculated by the Secretary for the adjustment in clause (i) exceeds 25 percent, the Secretary shall use 25 percent for the adjustment; and''; and

(B) in subparagraph (B), by striking ''2021 through 2023'' and inserting ''2026 through 2028''.

(4) FINAL YEAR ADJUSTMENT.—Section 741(c)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(c)(4)) is amended—

(A) striking ''2023'' each place it appears and inserting ''2028''; and

(B) striking ''2024'' and inserting ''2029''.

(d) FEE WAIVER OR REDUCTION; EXEMPTION FROM FEES.—Subsection (d) of section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) is amended to read as follows:

''(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from, or a reduction of, one or more fees assessed under subsection (a) where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.''.

(e) EFFECT OF FAILURE TO PAY FEES.—Section 741(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(e)) is amended by striking ''The Secretary may discontinue'' and inserting ''A request to establish a generic investigational new animal drug file that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for action by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue''.

(f) ASSESSMENT OF FEES.—Section 741(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(f)(2)) is amended by striking ''sponsors, and generic new animal drug products at any time'' and inserting ''products, generic new animal drug sponsors, and generic investigational new animal drug files at any time''.

(g) CREDITING AND AVAILABILITY OF FEES.—Section 741(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(g)) is amended—

(1) in paragraph (3), by striking ''2019 through 2023'' and inserting ''2024 through 2028'';

(2) by striking the following:

''(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for

fiscal year 2017 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.''; and

(3) by adding at the end the following:

''(5) RECOVERY OF COLLECTION SHORTFALLS.—The amount of fees otherwise authorized to be collected under this section shall be increased—

''(A) for fiscal year 2026, by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2024 falls below the amount of fees authorized for fiscal year 2024 under paragraph (3);

''(B) for fiscal year 2027, by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2025 falls below the amount of fees authorized for fiscal year 2025 under paragraph (3); and

''(C) for fiscal year 2028, by the amount, if any, by which the amount collected under this

section and appropriated for fiscal years 2026 and 2027 (including estimated collections for fiscal year 2027) falls below the amount of fees authorized for such fiscal years under paragraph (3).''.

(h) DEFINITIONS.—Section 741(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(k)) is amended—

(1) by redesignating paragraphs (8), (9), (10), and (11) as paragraphs (9), (10), (11), and (13), respectively;

(2) by inserting after paragraph (7) the following:

''(8) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG MEETING REQUEST.—The term 'generic investigational new animal drug meeting request' means a request submitted by a generic new animal drug sponsor to meet with the Secretary to discuss an investigational submission for a generic new animal drug.'';

(3) in paragraph (11) (as so redesignated), by adding at the end the following:

''(I) The activities necessary for exploration and implementation of the United States and European Union Mutual Recognition

Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the United States and United Kingdom Recognition Agreement Sectoral Annex for Pharmaceutical Good Manufacturing Practices, and future mutual recognition agreements, with respect to generic new animal drug products subject to review, including implementation activities prior to and following product approval.''; and

(4) by inserting after paragraph (11) (as so redesignated) the following:

''(12) REQUEST TO ESTABLISH A GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—The term 'request to establish a generic investigational new animal drug file' means the submission to the Secretary of a request to establish a generic investigational new animal drug file to contain investigational submissions for a generic new animal drug.''.

SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) is amended—

(1) in subsection (a), by striking ''2018'' and inserting ''2023'';

(2) by striking ''2019'' each place it appears in subsections (a) and (b) and inserting ''2024''; and

(3) in subsection (d), by striking ''2023'' each place it appears and inserting ''2028''.

SEC. 204. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as in effect on the day before the date of enactment of this title, shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2018, but before October 1, 2023, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2024.

SEC. 205. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2023, or the date of the enactment of this Act, whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this title, shall be assessed for abbreviated applications for a generic new animal drug and supplemental abbreviated applications for

a generic new animal drug received on or after October 1, 2023, regardless of the date of enactment of this Act.

SEC. 206. SUNSET DATES.

(a) AUTHORIZATION.—Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall cease to be effective October 1, 2028.

(b) REPORTING REQUIREMENTS.—Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) shall cease to be effective January 31, 2029.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2023, subsections (a) and (b) of section 206 of the Animal Generic Drug User Fee Amendments of 2018 (Public Law 115–234) are repealed.

○